IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	
AMERICAN HOME PRODUCTS CORPORATION	)	NO. 99-20593

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8450

Bartle, C.J. April 6, 2010

Betty Brown-Riddle ("Ms. Brown-Riddle" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. James E. Riddle, Ms. Brown-Riddle's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In July, 2004, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Randall G. Johnson, M.D. Based on an echocardiogram dated June 15, 2004, Dr. Johnson attested in Part II of claimant's Green Form that Ms. Brown-Riddle suffered from moderate aortic regurgitation and a reduced ejection fraction in the range of 40% to 49%.[4] Based

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3. (...continued)
for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

4. Dr. Johnson also attested that claimant suffered from mild
(continued...)

on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $486,424.[5]

In the report of claimant's echocardiogram, Dr. Johnson stated that Ms. Brown-Riddle had "[m]ild to moderate aortic insufficiency." Dr. Johnson did not specify a percentage as to the level of claimant's aortic regurgitation. Under the definition set forth in the Settlement Agreement, moderate aortic regurgitation is present where the regurgitant jet height ("JH") in the parasternal long-axis view (or in the apical long-axis view, if the parasternal long-axis view is unavailable) is equal to or greater than 25% of the left ventricular outflow tract height ("LVOTH"). See Settlement Agreement §§ I.22. & IV.B.2.c.(2)(a). Dr. Johnson also estimated claimant's ejection fraction as 48%. An ejection fraction is considered reduced for purposes of an aortic valve claim if it is measured as less than 50%. See id. § IV.B.2.c.(2)(a)iii).

In August, 2005, the Trust forwarded the claim for review by Michele Penkala, M.D., one of its auditing

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4. (...continued)
mitral regurgitation, an abnormal left ventricular end-systolic dimension equal to or greater than 45 mm by M-Mode or 2-D echocardiogram, and New York Heart Association Functional Class I symptoms. These conditions, however, are not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the aortic valve if he or she is diagnosed with moderate or severe aortic regurgitation and one of three complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(a). A reduced ejection fraction of less than 50% is one of the complicating factors needed to qualify for a Level II claim.

cardiologists. In audit, Dr. Penkala concluded that there was no reasonable medical basis for Dr. Johnson's finding that claimant had moderate aortic regurgitation. In support of this conclusion, Dr. Penkala explained that:

> I measured the JH/LVOTH to be 16-17% which clearly places the [aortic insufficiency] in the category of mild. Also it appears to be only mild by visual estimate. The measurements used for the moderate determination are not included on the tape.

Dr. Penkala also concluded that there was no reasonable medical basis for the attesting physician's conclusion that claimant had a reduced ejection fraction. In particular, Dr. Penkala found that:

> The [left ventricle] is at the upper limits of normal size. There are no wall motion abnormalities. From the parasternal views the endocardium is not well seen but from the apical views I thought that the [ejection fraction] was probably still >60%. I wouldn't quibble with someone saying that it was in the 50%-60% range as it could be at the upper end of this range but there is no evidence to support the [ejection fraction] being significantly reduced at 40-49%. I think that this determination is unreasonable.

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination denying Ms. Brown-Riddle's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[6] In contest, claimant argued that

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6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition (continued...)

under the reasonable medical basis standard, the attesting physician's conclusions should be accepted unless they are "extreme or excessive." Claimant also asserted that Dr. Johnson's conclusion as to claimant's level of aortic regurgitation was reasonable because it is consistent with a November 28, 2001 echocardiogram that claimant received under the Trust's Screening Program.[7] In the report of claimant's November 28, 2001 echocardiogram, the reviewing cardiologist, Sudhir Jain, M.D., concluded that Ms. Brown-Riddle had "[m]ild to moderate aortic valve insufficiency." Claimant further contended that "[q]uantifying the level of regurgitation shown on an echocardiogram is inherently subjective."[8] Finally, claimant suggested that the Trust was not properly applying the reasonable medical basis standard established in the Settlement Agreement

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6. (...continued)
of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Brown-Riddle's claim.

7. See Settlement Agreement § IV.A.1.a. (Screening Program established under the Settlement Agreement).

8. In support of this argument, claimant submitted excerpts of depositions of five (5) physicians from other proceedings. None of the testimony submitted by claimant, however, specifically addressed Ms. Brown-Riddle's echocardiogram.

and that the auditing cardiologist simply substituted her own opinion for that of the attesting physician.[9]

The Trust then issued a final post-audit determination again denying Ms. Brown-Riddle's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Brown-Riddle's claim should be paid. On June 21, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6384 (June 21, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on August 31, 2006, and claimant submitted a sur-reply on September 27, 2006. The Show Cause Record is now before the court for final determination. See Audit Rule 35.

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9. Claimant also contended that the Trust should ensure that its auditing cardiologists do not have any "biases" against claimants. As there is no evidence that the auditing cardiologist had a "bias," this issue is irrelevant for resolution of this claim. Similarly, claimant referenced, without any substantive discussion, a number of filings in MDL 1203. As claimant has not attempted to establish how these filings entitle her to Matrix Benefits, they are not pertinent to the disposition of this show cause claim.

The issues presented for resolution of this claim are whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's findings that Ms. Brown-Riddle had moderate aortic regurgitation and a reduced ejection fraction. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form that are at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Brown-Riddle reasserts the arguments that she made in contest. In addition, claimant argues that there is a reasonable medical basis for the attesting physician's finding of a reduced ejection fraction because the calculation of an ejection fraction is "highly subjective, with inter-reader variability of up to 10% being the norm."[10] Finally, claimant suggests that it is not uncommon for two cardiologists to review the same echocardiogram and to find different levels of regurgitation. According to claimant, "[n]either diagnosis is correct or incorrect; both fall within the realm of having a 'reasonable medical basis.'"

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10. Claimant did not provide any expert submission or cite any medical literature in support of this argument.

In response, the Trust disputes claimant's characterization of the reasonable medical basis standard. Moreover, the Trust argues that claimant failed to establish a reasonable medical basis for her claim because she did not rebut any of Dr. Penkala's specific findings. Finally, the Trust asserts that the results of a Screening Program echocardiogram do not support Ms. Brown-Riddle's claim for Matrix Benefits.

In her sur-reply, claimant argues that the Trust misapplies this court's statement in PTO No. 2640 that "a claimant with mitral regurgitation at 19.9% RJA/LAA, a level just below moderate, is ineligible for benefits." PTO No. 2640 at 8 n.5 (Nov. 14, 2002). Ms. Brown-Riddle also submits that her definition of reasonable medical basis is supported by two dictionary definitions and a declaration by an expert in interpreting the English language. In addition, claimant asserts that the Trust incorrectly relies on PTO No. 5229 for the proposition that a finding of mild to moderate regurgitation cannot establish a reasonable medical basis for a finding of moderate regurgitation. Finally, claimant argues that Dr. Penkala erred in determining that there was no evidence to support a finding that Ms. Brown-Riddle has a reduced ejection fraction because the M-Mode report "clearly evidence[s]" such condition.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, and of crucial importance, claimant does not adequately contest Dr. Penkala's

findings of mild aortic regurgitation and a normal ejection fraction. Despite the opportunity in the contest period to present additional evidence in support of her claim, Ms. Brown-Riddle rests only on Dr. Johnson's check-the-box diagnoses on her Green Form and the reports of several echocardiograms. Claimant never identified any particular error in Dr. Penkala's measurements or conclusions.[11] Mere disagreement with the auditing cardiologist without identifying and substantiating any specific errors by the auditing cardiologist is insufficient to meet a claimant's burden of proof.[12] On this basis alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.

We also disagree with claimant's characterization of the reasonable medical basis standard. We are required to apply the standards delineated in the Settlement Agreement and the Audit Rules. The context of these two documents leads us to interpret the reasonable medical basis standard as more stringent than claimant contends, and one that must be applied on a case-by-case basis. Here, Dr. Penkala determined in audit, and Ms. Brown-Riddle does not adequately dispute, that the attesting

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11. Although claimant argues that the "M-Mode report supports Dr. Johnson's position rather than Dr. Penkala's position," Ms. Brown-Riddle does not provide any support for this assertion.

12. We also reject claimant's assertion that there is a reasonable medical basis for her claim because Dr. Johnson and Dr. Jain each concluded that she had mild to moderate aortic regurgitation. A claimant cannot establish a reasonable medical basis for his or her claim simply by accumulating cardiologist opinions or echocardiogram reports.

physician's findings of moderate aortic regurgitation and a reduced ejection fraction were unreasonable. Specifically, Dr. Penkala "measured the JH/LVOTH to be 16-17% which clearly places the [aortic insufficiency] in the category of mild. Also, it appears to be only mild by visual estimate." Dr. Penkala further noted that "[t]he measurements used for the moderate determination are not included on the tape." With respect to the level of claimant's ejection fraction, Dr. Penkala specifically concluded that "the [ejection fraction] was probably still > 60%. I wouldn't quibble with someone saying that it was in the 50-60% range ... but there is no evidence to support the [ejection fraction] being significantly reduced at 40-49%."[13] Contrary to claimant's argument, Dr. Penkala properly applied the reasonable medical basis standard established under the Settlement Agreement.

Moreover, we reject claimant's assertion that she is entitled to Matrix Benefits because an echocardiogram that was conducted in the Screening Program for Fund A Benefits purportedly supports the attesting physician's finding of moderate aortic regurgitation. See Settlement Agreement § IV.A.

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13. Similarly, we disagree with claimant that the conflict between the attesting physician and the auditing cardiologist is due to the "subjective nature of echocardiography." Nor has Dr. Penkala merely substituted her opinion for that of the attesting physician. Instead, Dr. Penkala specifically found that there was no reasonable medical basis for the attesting physician's findings of moderate aortic regurgitation and a reduced ejection fraction. Neither claimant nor claimant's attesting physician, however, adequately refuted or responded to these determinations.

The Settlement Agreement clearly provides that the sole benefit that an eligible class member is entitled to receive for an echocardiogram performed in the Screening Program is a limited amount of medical services or cash payment:

> All Diet Drug Recipients in Subclass 2(b) and those Diet Drug Recipients in Subclass 1(b) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, will be entitled to receive, at the Class Member's election, either (i) valve-related medical services up to $10,000 in value to be provided by the Trust; or (ii) $6,000 in cash.

Id. § IV.A.1.c. Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

Indeed, this conclusion is confirmed by the Settlement Agreement provisions concerning claimants eligible for Matrix Benefits. Specifically, claimants receiving a diagnosis of FDA Positive or mild mitral regurgitation merely become eligible to seek Matrix Benefits. See id. § IV.B.1. Further, adopting claimant's position would be inconsistent with Section VI.E. of the Settlement Agreement, which governs the audit of claims for Matrix Benefits, as well as this court's decision in PTO No. 2662, which mandated a 100% audit requirement for all claims for Matrix Benefits. See PTO No. 2662 at 13 (Nov. 26, 2002). As nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram for purposes of Fund A Benefits results in an immediate entitlement to Matrix

Benefits, we decline claimant's request to interpret the Settlement Agreement in this fashion.[14]

Finally, claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that Ms. Brown-Riddle has a reduced ejection fraction is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's finding of a reduced ejection fraction in the range of 40% to 49% cannot be medically reasonable where the auditing cardiologist concluded that claimant's ejection fraction exceeded 60%.[15] Adopting claimant's argument on inter-reader variability would expand the range for a reduced ejection fraction by 10% and would allow a claimant to recover Matrix Benefits for damage to the aortic valve with an ejection fraction as high as 59%. This result

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14. In any event, the report for the Screening Program echocardiogram simply states that the echocardiogram demonstrated "mild to moderate aortic insufficiency." Absent medical support for claimant's proposition that the Screening Program echocardiogram demonstrates the requisite level of aortic regurgitation required for a claim for Matrix Benefits, the Screening Program echocardiogram does not establish a reasonable medical basis for Ms. Brown-Riddle's claim.

15. Moreover, the auditing cardiologist took into account the concept of inter-reader variability as reflected in her statement that "I wouldn't quibble with someone saying that it was in the 50-60% range as it could be at the upper end of this range but there is no evidence to support the [ejection fraction] being significantly reduced at 40-49%. I think that this determination is unreasonable."

would render meaningless this critical provision of the Settlement Agreement.[16]

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate aortic regurgitation and a reduced ejection fraction in the range of 40% to 49%. Therefore, we will affirm the Trust's denial of Ms. Brown-Riddle's claim for Matrix Benefits and the related derivative claim submitted by her spouse.

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16. Even if we accepted claimant's inter-reader variability argument, Ms. Brown-Riddle's claim still would fail because the auditing cardiologist determined that claimant's ejection fraction exceeded 60%, which could, under claimant's theory, only be reasonably read as more than 50%. An ejection fraction is considered reduced for purposes of a claim for damage to the aortic valve only if it is less than 50%. See Settlement Agreement § IV.B.2.c.(2)(a)iii).